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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,926	10/29/2001	David M. Deboer	88066-5199	2483
28765	7590	08/25/2005	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,926

Applicant(s)

DEBOER ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,9,11-13 and 16-25 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,9 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>prior art Fig 10 & 11</u> |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,3-5, 16-17, 20-22,24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Lilley et al. (U.S. Patent No. 5599,302).

Lilley et al. disclose an injection dev. Comprising a housing, a nozzle assembly, a plunger, a trigger assembly an energy generating source and a fixed injection assisting probe comprising a body having a discharged channel and a orifice at the distal end. Lilley et al. teach the orifice having a diameter of about 0.07-0.4 mm which is encompassed by 0.004 to 0.012 inches. Looking at 1-6 and specifically figures 10-11, the length of the discharge channel is at least 0.024 inches and thus the length to orifice ratio is inherently greater than 6/1 or greater than 9/1 ratios. In light of applicant's

amendment to the claims to the length to diameter ratio is greater than 6/1. Lilley et al. still anticipates the claims. Applicant has not narrowed the claim to where the diameter of the channel is located. Thus in the broadest interpretation, Lilley et al. rejection is being maintained. See attached. The channel is considered to be the length of the probe in figure 10 and 11. The orifice is at the distal end but the channel is from the distal end all the way to the proximal end. As clearly shown the length is much larger than the diameter at an average of the diameter along the length or even at selected diameters taken along the x-axis. With respect to claim 22, since the lumen is circular, it would be inherent that the diameter is constant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al. (U.S. Patent No. 5,599,302).

See Lilley et al. above. However, Lilley et al. does not disclose the ratio between 9/1 and 20/1. Varying the length of the discharge channel would have been a mere design choice to one of ordinary skill in the art. It would have been obvious to one of ordinary skill in the art to modify the length as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended target (ear) area

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depending on the size of the ear of the patient where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

Further as evidenced by Masano, the teaching of the ratio of the length to the diameter is varied in order to provide for delivery of different viscosity of materials.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-7 of U.S. Patent No. 6,309,371. Although the conflicting claims are not identical, they are not patentably distinct from each other the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim a an injection device having a housing , a nozzle assembly , a

plunger, a trigger assembly , an energy generating source a probe having a discharge channel and an orifice with diameters and lengths associated therewith. The patent claims recite an injection device having a housing , a nozzle assembly , a trigger assembly , a plunger, an energy generating source and a probe tip with a discharge channel , a probe tip , a plunger receptor, a retraction element and a probe with a discharge channel with diameters and lengths associated therewith. Since a broad interpretation of an injection assisting probe includes a fixed injection probe, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,309,371 patent.

Response to Arguments

Applicant's arguments filed 06/16/05 have been fully considered but they are not persuasive. Applicant's arguments that the length to diameter ratio is not clearly shown is not persuasive. Applicant referred to figures 10-11. The length of the discharge tube is shown clearly with a taper. See element 24 and 28. The orifice 24 is very small and it is considered to be clearly shown that the length of the channel to the diameter of the orifice is greater than 6/1.

With respect to the double patenting rejection, Applicant has elected a different patentably distinct species. However, applicant's claims are broader in scope than the parent claims. The double patenting rejection is maintained.

In response to applicant's argument that the examiner's conclusion of obviousness is not foreseen or suggested in the prior art, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh


LOAN H. THANH
PRIMARY EXAMINER 8/20/05

FIG. 10

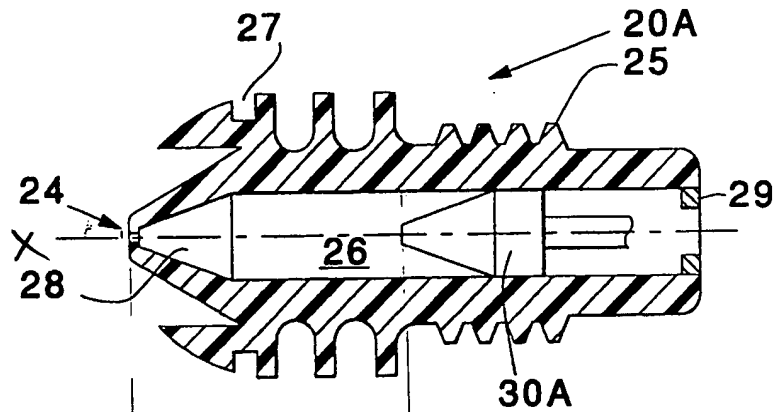


FIG. 11

